

## For immediate release

Alcon Updates Filing Status of RETAANE® New Drug Application
Therapy is on track for launch in first half of 2005.

**FORT WORTH, Texas – June 30, 2004** – Alcon, Inc. (NYSE:ACL) announced that it has filed the second portion of its "rolling" New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for RETAANE® 15mg (anecortave acetate for depot suspension), an investigational treatment for preserving the vision of patients with all forms of wet age-related macular degeneration (AMD). The announcement was made today during a meeting of international retinal experts in Amsterdam, Holland.

RETAANE® depot is a fast track designated product that was also accepted into FDA's new Pilot 1 Continuous Marketing Application (CMA) program because of its potential as a treatment for a significant unmet medical need in patients with a serious condition. The "rolling" NDA permitted under this new FDA program allows designated NDAs to be submitted in specified reviewable units as each is completed, rather than as one package when the last unit is completed. The three main reviewable units are the Chemistry, Manufacturing and Controls (CMC) unit; the Pre-Clinical unit; and the Clinical unit. The fast-track designation provides a performance target for the FDA to complete its review of each unit within six months of its submission.

The FDA has completed its initial review of the RETAANE® depot CMC reviewable unit, which was filed in 2003. Furthermore, the pre-approval inspection of Alcon's manufacturing facility has been completed with no negative findings (no 483 observations). Alcon also submitted the Pre-Clinical unit for RETAANE® depot in March of this year, and has responded to all questions to date.

Alcon plans to complete the submission of the RETAANE® depot NDA with the filing of the Clinical unit in the fourth quarter of 2004. This unit will incorporate the twelve-month results from the on-going, multi-center, phase III clinical trial comparing RETAANE® depot with photodynamic therapy (PDT) in 530 patients with wet AMD, along with results from other clinical studies completed during the development program. If approved, consistent with the spirit of the CMA Pilot, Alcon is prepared to quickly make RETAANE® depot available for treating wet AMD.

"By piloting new review programs such as the Continuous Marketing Application program, the FDA is taking significant steps to ensure that safe and effective treatments that address significant unmet medical needs are efficiently made available to the American public," said Scott Krueger, Ph.D., Alcon's Vice President of Regulatory Affairs. "In anticipation of the upcoming twelve-month clinical safety and efficacy data from our ongoing Phase III study, we are looking forward to submitting for FDA review the final NDA unit for RETAANE® depot. Once we have filed this last unit, we believe the drug development program for RETAANE® depot will have generated a compelling database that supports its use as a treatment for wet AMD."

#### **About AMD**

Age-related macular degeneration causes damage to the macula – the light-sensitive cells at the center of the retina at the back of the eye. The macula is responsible for our ability to see with enough detail to read, drive, watch television and perform other activities that require focused, straight-ahead vision, as well as providing information that allows us to perceive colors; thus, allowing one to maintain independence in daily activities.

There are two types of AMD – "dry," or atrophic or non-exudative, and "wet," or exudative. Although the wet form of AMD constitutes only 10-15 percent of all AMD cases, it is responsible for 90 percent of blindness attributable to this condition. Today, wet AMD is the leading cause of blindness in industrialized nations in people over the age of 50, primarily because there is a lack of effective treatments for the disease. Currently, there is no approved treatment for dry AMD. The two currently approved treatments for wet AMD – laser photocoagulation and photodynamic therapy – are appropriate for only a percentage of patients.

# **About RETAANE®** Depot

Anecortave acetate, the active ingredient in RETAANE® 15 mg (anecortave acetate for depot suspension), is an angiostatic cortisene that inhibits the abnormal growth of blood vessels – a process scientifically known as angiogenesis. Angiostatic cortisenes were derived from the steroid class and engineered to remove chemical groups responsible for unwanted glucocorticoid effects, such as the development of cataracts and elevated intraocular pressure leading to glaucoma, while preserving angiostatic (or anti-neovascular) potency.

Some investigational therapies attempt to block only one growth factor such as vascular endothelial growth factor (VEGF), thus still allowing other growth factors, such as basic fibroblast growth factor (bFGF), to signal the endothelial cells and commence the angiogenesis process. Angiostatic cortisenes are able to block signals from multiple growth factors because they act downstream and independent of the initiating angiogenic stimuli thus inhibiting angiogenesis subsequent to the angiogenic stimulation.

RETAANE® depot is the only therapy for AMD that uses the unique delivery system of posterior juxtascleral depot (PJD). During the procedure, RETAANE® 15 mg is drawn into a blunt-tipped, curved cannula and then delivered in direct contact with the outer surface of the sclera without puncturing the eyeball. This method of delivery for RETAANE® depot avoids the risk of intraocular infection and retinal detachment, the most common side effects associated with frequently injecting therapeutic agents directly into the eye. RETAANE® depot requires less frequent administration (once every six months) compared to some other investigational angiogenesis inhibitors, which are injected into the eye as often as nine to 12 times a year. According to an independent safety panel, no clinically relevant side effects were associated with RETAANE® depot or the PJD procedure.

#### **About Alcon**

Alcon, Inc. is the world's leading eye care company. Alcon, which has been dedicated to the ophthalmic industry for over 50 years, develops, manufactures and markets pharmaceuticals, surgical equipment and devices, contact lens solutions and other vision care products that treat diseases, disorders and other conditions of the eye. Alcon has been conducting retinal research for more than 15 years and is the world's leading provider of surgical equipment used by vitreoretinal specialists who treat patients with AMD and other retinal diseases.

#### Caution Concerning Forward-Looking Statements.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, relating principally to our ability to complete clinical trials for Anecortave Acetate and file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and the expected benefits of Anecortave Acetate in treating exudative age-related macular degeneration (AMD). These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by our forward-looking statements. These statements reflect the views of our management as of the date of this press release with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward- looking statements. Factors that might cause future results to differ include, but are not limited to, the following: we may never submit an NDA for anecortave acetate to the FDA, or submission and/or approval of the NDA may take longer than we expect; treatments developed by other companies may reach the market sooner or prove to be more effective than anecortave acetate: challenges inherent in new product marketing; and government regulation and legislation. You should read this press release with the understanding that our actual future results may be materially different from what we expect. Except to the extent required under the federal securities laws and the rules and regulations promulgated by the Securities and Exchange Commission, we undertake no obligation to publicly update or revise any of these forward- looking statements, whether to reflect new information or future events or circumstances or otherwise.

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